UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	)	

BRIEF OF THE UNITED STATES AS AMICUS CURIAE

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STATEMENT

The United States Department of Justice (DOJ), on behalf of the Secretary of Health and Human Services (Secretary), submits this *amicus curiae* brief in response to the Court's request that the Secretary explain his views on the term "average wholesale price" (AWP), as reflected in the Medicare Act, *see* 42 U.S.C. §§ 1395 *et seq.*, and federal regulations.

Since Medicare's inception, Congress and the Secretary have sought to balance the goals of fairly compensating health care providers for their services while managing program expenditures in a fiscally prudent manner. To achieve that goal, Congress adopted the broad parameters of a system that would reimburse health care providers and suppliers based on their reasonable costs and charges for the services that they rendered. Congress directed the Secretary of Health, Education and Welfare (and later the Secretary of Health and Human Services) to implement regulations that, among other things, established the reimbursement rates under the sweeping new system. While the mechanisms that the Secretary employed for setting Medicare reimbursement amounts continue to evolve, these elemental principles of fair compensation and fiscal prudence govern to this day.

Likewise, with regard to Part B drug payments, since the beginning of the Medicare program, the Secretary's general policy has been to base payments on estimated acquisition costs consistent with reasonable charge principles. *See* 56 Fed. Reg. 25792, 25800 (June 5, 1991). The introduction of the term "national average wholesale price" into the payment lexicon did not change these animating principles.

Contrary to the arguments put forth by the Track 1 Defendants, that the term "national average wholesale price" was not defined with mathematical precision, or that it could have reflected a range of prices, does not undercut the Secretary's programmatic objective to pay for

drugs consistent with reasonable charge principles. The Medicare regulatory scheme contains many general standards that the Secretary expects providers and suppliers to interpret in good faith when seeking payments from the Government. Nor can the Secretary's reliance on national publications of wholesale pricing data be credibly characterized as an abandonment of those payment goals. While hindsight may have shown that some of the data in the compendia were not reliable indicia from which to estimate supplier acquisition costs for certain drugs, nothing in the regulatory history indicates that the Secretary sought to adopt a benchmark that exhibited no rational boundaries or was completely unmoored from reasonable charges in the marketplace.

The Track 1 Defendants urge that the Secretary meant for the regulatory term "national average wholesale price" to be defined by and limited to whatever prices drug manufacturers reported to the national price listings. But given the legislative and regulatory history of the Medicare program, and the Part B drug benefit in particular, it is simply unfathomable that the Secretary, who set reimbursement rates in every other aspect of the Medicare program, implicitly meant for the industry, and not the agency, to set drug reimbursement rates. Such an approach would constitute a radical departure from the Medicare goal of fiscal prudence and is simply not borne out by the plain statutory language or the legislative history.

As this court is aware, the starting point in construing a statute is its plain meaning. In this case, the plain meaning of "average wholesale price" comports with the Medicare Act and its programmatic payment objectives. Accordingly, the Court should not follow the wayward path of the Track 1 Defendants, which runs afoul of this bedrock principle of statutory construction and is contrary to the clear goals of the Medicare program, and instead should

employ the plain meaning of the term "average wholesale price" in evaluating the claims in this action.

DISCUSSION

I. Statutory and Regulatory Background

A. The Medicare Program and Historical Efforts to Contain Program Spending

Congress established the Medicare program in 1965 as a federally funded insurance program for the elderly and disabled under Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395 *et seq*. (Medicare Act).[1] The Secretary administers the Medicare program through the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration (HCFA)).

Since the program's inception, Congress and the Secretary have sought to balance the goals of fairly compensating providers and suppliers for their services while managing Medicare expenditures in a fiscally prudent manner. Traditionally, Congress and the Secretary advanced these goals by limiting Medicare payments to the "reasonable costs" of Part A services and the "reasonable charges" of Part B services, and setting those limits based on a provider's actual costs or a supplier's actual, customary or prevailing charges. Pub. L. 89-97, § 1833(a), 79 Stat. 286 (1965) (codified at 42 U.S.C. § 1395l(a)(2)); 32 Fed. Reg. 12599 (Aug. 31, 1967); *see*

[1] Today, the Medicare program consists of four parts. Part A provides insurance coverage for inpatient hospital care, home health care, and hospice services. *See* 42 U.S.C. §§ 1395c-1395i-5. Part B provides voluntary supplemental insurance for physician services, outpatient hospital services, and other health services. *See* 42 U.S.C. §§ 1395j to 1395w-4. Medicare Part C (formerly Medicare + Choice, now known as Medicare Advantage) permits managed care and private fee-for-service plans to offer Medicare benefits in addition to those available under Medicare Parts A and B. *See* 42 U.S.C. §§ 1395w-21 to 1395w-29. Part D, which Congress established through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, provides a voluntary prescription drug benefit. *See* 42 U.S.C. §§ 1395w-101 to 1395w-105.

S. Rep. No. 404, 89th Cong., 1st Sess., *reprinted in* 1965 U.S.C.A.A.N. 1943, 1976-77, 1984-85. Congress intended that the "reasonable cost," however determined by the Secretary, "approximate as closely as practicable the actual cost (both direct and indirect) of services rendered to the beneficiaries of the program[.]" *Id.* at 1976. As for "reasonable charge," Congress wanted Medicare payments to be limited by what a physician "customarily" charged patients for a particular service or the "prevailing" charges for a service in a given locality. *Id.* at 1985. While what is considered "reasonable" has evolved, these animating principles continue to reflect Congress' and the Secretary's best estimation of the appropriate balance between the goals of compensating hospitals and physicians fairly for their services and protecting the financial integrity of the Medicare program.[2]

As Medicare expenditures have grown, Congress and the Secretary have increasingly restricted how much Medicare reimburses for covered services. In the Part A context, one of

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[2] As one court described the Part B program:

> Medicare Part B, like many statutes, embodies a compromise between ideals of achievement and economic feasibility that puts its basic purposes in tension. The Act seeks to "make the best of modern medicine more readily available to the aged," but it tries to do so by covering only "reasonable and necessary" care in a manner that will ensure the financial integrity of the system. Perhaps the clearest indication of the statute's competing goals appears in its provision establishing that health care services will generally be covered at a statutorily-defined percentage of their cost. 42 U.S.C. § 1395l (West 1992 & Supp. 1998). Through this provision, the Act makes all levels of reasonable and necessary medical care more readily available to the aged, while at the same time discouraging excessive expenditure by requiring beneficiaries to pay for a proportionate share of the costs of the services they use.

TAP Pharmaceuticals v. U.S. Dep't of Health and Human Services, 163 F.3d 199, 204 (4th Cir. 1998) (emphasis in original).

Congress' earliest cost containment measures was to refine the definition of "reasonable cost" to mean "the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services[.]" Pub. L. 92-603; § 223 (1972) (codified at 42 U.S.C. § 1395x(v)(1)(A)). Congress passed this amendment to introduce considerations of cost efficiency into the delivery of Part A services:

> Health care institutions, like other entities in our economy, should be encouraged to perform efficiently and when they fail to do so should expect to suffer the financial consequences. . . . It is believed that [these objectives] can only be accomplished by reimbursement mechanisms that limit reimbursement to the costs that would be incurred by a reasonably prudent and cost-conscious management.

H.R. Rep. No. 231, 92nd Cong., 2nd Sess. (1972), *reprinted at* 1972 U.S.C.C.A.N. 4989, 5069. "In short, Congress did not intend to shield the medical decision-making process from financial consequences." *American Medical Ass'n v. Matthews*, 429 F. Supp. 1179, 1202 (N.D. Ill. 1977).

Over time, Congress has taken additional steps to cabin Medicare Part A expenditures. For example, in 1982, Congress imposed a ceiling on the rate of increase of allowable inpatient operating costs. *See* Tax Equity Act and Fiscal Responsibility Act of 1982, Pub. L. 97-248, 96 Stat. 324 (1982) (codified at 42 U.S.C. § 1395ww(b)). Then, in 1983, Congress moved hospital reimbursement away from the "reasonable cost" system and established the prospective payment system, under which providers would be reimbursed according to fixed rates based on the estimated costs associated with inpatient care. *See* Social Security Amendments of 1983, Pub. L. 98-21, 97 Stat. 65 (1983) (codified at 42 U.S.C. § 1395ww(d)). Congress designed this measure to enhance "the Medicare program's ability to act as a prudent purchaser of services and to provide increased predictability regarding payment amounts for both the Government and

hospitals." H.R. Rep. No. 25, 98th Cong., 1st Sess. 132 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 351.

Similar goals of fiscal prudence govern Part B. In addition to having Medicare beneficiaries share the costs of covered services they receive, *see* 42 U.S.C. §§ 1395j, 1395r-1395t, Medicare Part B limits coverage to those services determined to be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Moreover, Congress has indicated that the "reasonable charge" system should be animated by similar considerations of necessity and efficiency used in the Part A context when determining "reasonable cost." *See Matthews*, 429 F. Supp. at 1193 (discussing applicability of 42 U.S.C. § 1395x(v)(1)(A) to "reasonable charge" payments). To that effect, Congress amended the Medicare Act to provide that for medical supplies, services and equipment that did not vary in quality from one supplier to another, charges could not exceed the lowest charge levels at which such services, supplies and equipment are widely and consistently available in a locality. Pub. L. 92-603; § 223 (1972) (codified at 42 U.S.C. § 1395u(b)(3)); see 42 C.F.R. 405.502.

Bound by these broad statutory principles, Medicare historically paid the "reasonable charge" for physicians' services by limiting Part B payments to the lowest of: (1) the physician's actual charge, (2) the physician's customary charge,[3] or (3) the prevailing charge[4] in the physician's locality for similar services. *See* 42 U.S.C. §§ 1395l(a); 1395u(b); 42 C.F.R.

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[3] The customary charge limit was defined as the median amount that the physician charged for a given service during the course of an annual data collection period. *See* 42 C.F.R. § 405.503.

[4] The prevailing charge limit was set at an amount high enough to cover 75 percent of the customary charges made for similar services in a locality. *See* 42 C.F.R. 405.504(a)(2)(i)(1980).

§§ 405.500 *et seq.* Moreover, since the enacting statute, Medicare carriers have been required to limit the "reasonable charge" to an amount not in excess of that which the carrier paid its own (non-Medicare) policyholders and subscribers "for comparable services under comparable circumstances." S. Rep. No. 404, 89th Cong., 1st Sess., *reprinted in* 1965 U.S.C.A.A.N. at 85; *see* 42 U.S.C. § 1395u(b)(3).

As it did in the Part A context, Congress took additional steps to cabin Part B spending. Most significantly, in 1989, confronted with "unacceptably high annual rates of increase in Medicare expenditures for physicians' services," 56 Fed. Reg. 59813 (Nov. 25, 1991), Congress reformed Part B physician payments by replacing the "reasonable charge" system with a fee schedule system. *See* Pub. L. 101-239; H. Conf. Rep. No. 386, 101st Cong., 1st Sess. (1989), *reprinted at* 1989 U.S.C.C.A.N. 3018, 3341-45. Under this new system, to be effective January 1, 1992, Congress set payment for physicians' services at the lesser of the physician's actual charge or the fee schedule amount, as established by the Secretary.[5] *See* 42 U.S.C. §§ 1395l, 1395w-4(a)(1). Since then, Congress has continued to move Part B covered services and supplies under fee schedule payment systems, as it did in 1997 when it authorized the Secretary to establish fee schedules for the bulk of the remaining Part B covered supplies and services still reimbursed under the "reasonable charge" system. *See* Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, 111 Stat. 462-463, § 4315 (1997).

[5] The fee schedule amount reflected national uniform relative values for all physician services, times a conversion factor specific to each year that takes into account increases in the Medicare Economic Index, times a geographic adjustment factor. *See* 42 U.S.C. §§ 1395w-4(b)(1), (c)(2), (d), (e)(2).

B. Part B Drug Coverage and Payment

1. Part B Covered Drugs

To this day, Medicare Part B covers only a limited number of prescription drugs. *See* 68 Fed. Reg. 50428, 50429 (Aug. 20, 2003). These drugs generally fall into three broad categories. First, Part B covers injectable or intravenous drugs furnished "incident to" a physician's services.[6] 42 U.S.C. § 1395x(s)(2). These drugs, which include injectable and intravenous cancer treatment drugs, constitute the lion's share of Medicare Part B drug expenditures. *See* 68 Fed. Reg. at 50429. Second, Part B pays for drugs that are administered through covered durable medical equipment, like nebulizers or pumps. Common drugs in this category are the inhalation drugs albuterol sulfate and ipratropium bromide. *See id.* Finally, over time, Congress has expanded Part B coverage to certain additional drugs, including immunosuppressive drugs, certain oral anti-cancer drugs, oral anti-emetic drugs, and influenza and hepatitis vaccines. *Id.*

2. Medicare Drug Payments Have Historically Been Targeted at Estimates of Supplier Acquisition Cost

As they did in connection with Medicare Parts A and B generally, Congress and the Secretary have, over time, increasingly restricted what Medicare will consider "reasonable" and therefore reimbursable for drugs covered under Part B. Prior to 1992, neither the Medicare Act nor regulations expressly adopted AWP as a basis for payment for drugs provided under Part B. Instead, Medicare generally paid for covered drugs, like many items and services covered under Part B, under the "reasonable charge" system. *See* 42 U.S.C. §§ 1395l, 1395u(o). *See also TAP,*

[6] Section 1395(x)(s)(2) provides that these "incident to" drugs (1) are not usually self-administered, (2) are provided incident to a physician's professional services to patients in his office, (3) are of a kind commonly furnished in physicians' offices, and (4) are commonly rendered without charge or included in the physician's bill. *See* 42 U.S.C. 1395x(s)(2).

163 F.3d at 202 n.1; *Matthews*, 429 F. Supp. at 1194. The Secretary first passed a regulation regarding Part B covered drugs in 1991 when he limited Medicare payments to the lower of the estimated acquisition cost or the national average wholesale price of a drug. 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991) (final rule).[7] This regulation governed Part B drug payments until 1997, when Congress amended the Medicare Act and set Part B drug payments at 95 percent of the average wholesale price. See Pub. L. 105-33, 111 Stat. 462-463 (1997). The Secretary amended its Medicare regulations in 1998 to conform with the BBA amendment and, effective January 1, 1999, Medicare paid the lesser of the supplier's actual charge or 95 percent of the national average wholesale price. 63 Fed. Reg. 58814, 58905 (Nov. 2, 1998).[8] This payment system remained in place until 2003, when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act (MMA). Pub L. 108-173, 117 Stat. 2066 (2003). Under the MMA, Congress limited Medicare drug payments for most Part B drugs to 85 percent of the average wholesale price beginning April 1, 2004, and to 106 percent of the "average sales price" (ASP) starting January 1, 2005. *Id.* at § 2238 (amending 42 U.S.C. § 1395w-3).

Thus, while the mechanisms for determining "reasonable charge" have changed, Medicare regulations (for the time period at issue) provided for payments for most Part B drugs to be based on the lower of estimated acquisition cost or the national average wholesale price. *See* 56 Fed. Reg. 25792, 25800 (June 5, 1991); 56 Fed. Reg. 59502, 59507 (Nov. 25, 1991).

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[7] For multiple source drugs, the Secretary set Medicare payments at the lower of the estimated acquisition cost or the median average wholesale price for all sources of the drug. *Id.*

[8] For multiple source drugs, the Secretary defined Part B drug payments as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. *Id.*

We discuss the statutory and regulatory history of the Part B drug benefit in more detail below.

a. Pre-1991 Regulatory Drug Payment Efforts

Although the Secretary first passed a regulation expressly addressing "incident to" drug payments in 1991, Congress and the Secretary had ventured into Medicare drug payments on two earlier occasions. In 1974-1975, the Secretary promulgated regulations (Maximum Allowable Cost (MAC) regulations) that established a method to limit payments for drugs federally subsidized by the Medicare and Medicaid programs.[9] 40 Fed. Reg. 32284 (July 31, 1975) (final rule); *see* 39 Fed. Reg. 40302 (Nov. 15, 1974) (proposed rule). In 1988, Congress enacted the Medicare Catastrophic Coverage Act (MCCA), Pub. L. 100-360, 102 Stat. 683, which, among other things, created a Medicare Part B outpatient drug benefit, and in 1989, the Secretary proposed rules implementing that drug benefit. 54 Fed. Reg. 37208 (Sept. 7, 1989).

[9] The Secretary promulgated the MAC regulations out of a desire to capitalize on the cost-savings available from the use of multiple-source drugs:

> What the Secretary is determining by issuing the MAC regulation is that portions of the costs of certain drugs are unnecessary to the efficient delivery of quality health care. This determination is based upon a recognition of the fact that a number of drugs containing the same active ingredients in the same dosage forms and strengths are available from different formulators and labelers at significantly different prices. In light of this fact, and in the interest of the efficient administration of the duties with which the Secretary is charged, consistent with quality care, the MAC regulation is issued to take advantage of these varying multiple-source drug prices.

40 Fed. Reg. at 32288.

Although both measures were ultimately repealed,[10] these regulatory forays highlight that Medicare drug payments were based on estimates of what suppliers were paying for drugs. For example, under the MAC system, the Secretary limited Medicare payments for multiple-source drugs as the lowest of: (1) the MAC price, which was to be based in part on survey data of actual pharmacy invoices,[11] (2) the acquisition cost of the drug, or (3) the provider's usual and customary charge to the public for the drug. *See* 40 Fed. Reg. at 32304. As defined by the Secretary, the acquisition cost was "the price generally and currently paid by providers for a drug marketed or sold by a particular formulator or labeler in the package size of the drug most frequently purchased by providers." *Id.*

Similarly, under the MCCA proposed regulations, Medicare payments for non-multiple-source drugs would have been limited to the lesser of (1) the 90th percentile of actual charges for the drug nationwide during the previous annual payment calculation period, or (2) a national payment limit that was to be set by the Secretary. 54 Fed. Reg. at 37210, 37212, 37214-215. The national payment limit, in turn, was to be set at the lower of the (1) "survey average price" based on biannual surveys of actual selling prices as reported by direct sellers, wholesalers, or

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[10] The Secretary repealed the MAC payment limitation in 1987 as it applied to Medicare. *See* 52 Fed. Reg. 28648 (July 31, 1987). Congress repealed the MCCA through the Medicare Catastrophic Coverage Repeal Act of 1989, Pub. L. 101-234, 103 Stat. 1979, and HCFA subsequently withdrew its proposed regulation. 55 Fed. Reg. 9740 (March 15, 1990).

[11] Under the regulation, the Pharmaceutical Reimbursement Board (PRB) set the MAC limit for multiple source drugs based on two sources of data: the HCFA survey and the Red Book. 47 Fed. Reg. 27968 (June 28, 1982). The HCFA survey data, which the agency purchased from a commercial source, reflected the results of a monthly survey of invoices from 1,000 pharmacies nationwide. *Id.* The HCFA survey price was set at the 70th percentile of all the pharmacy invoice prices. *Id.* To the extent pricing data was available from both sources, the PRB set the MAC limit at the lower of the two prices. *Id.*

pharmacies to the Secretary, or, (2) "published average price" reflected in the Red Book, the American Druggist Blue Book, or Medi-Span, if the Secretary determined the use of a survey price to be inappropriate. *Id.* at 37214-15.

Although both regulations contemplated the Secretary considering published wholesale prices as one source of data, the overall payment scheme reflected an intent to base Medicare payments on an amount reflective of acquisition prices in the marketplace.

C. 1991 National Average Wholesale Price as a Benchmark

As mentioned above, in 1989, Congress reformed Part B physician payments and directed the Secretary to promulgate regulations implementing the physician fee schedule, which was to take effect January 1, 1992. In 1991, the Secretary published the proposed and final physician fee schedules. *See* 56 Fed. Reg. 25792 (June 5, 1991) (proposed rule); 56 Fed. Reg. 59502 (Nov. 25, 1991) (final rule). Although the Secretary believed that Part B "incident to" drugs should also be reimbursed under a fee schedule, the large number of drugs and dosages prevented the agency from establishing one at that time. *Id.* at 25800. Nevertheless, in an effort to establish more uniformity in Part B drug payments among the Medicare carriers, the Secretary formalized the method that Medicare carriers were to use to set the "reasonable charge" for a Part B drug. The final rule provided as follows:

> (b) Methodology. Payment for a drug [not paid on a cost or prospective basis] is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste and spoilage.
>
> (c) Multiple-Source drugs. For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b)

> of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

56 Fed. Reg. 59621 (promulgating 42 C.F.R. § 405.517).

The final rule was consistent in both form and substance with the agency's prior efforts at limiting drug payments, as well as the Part B payment scheme generally. First, the final rule continued to reflect the Secretary's intention to limit Part B drug payments to an amount related to supplier acquisition costs. The Secretary most directly effectuated this intent by issuing a regulation that would anchor Part B drug payments to a drug's estimated acquisition cost ("EAC"), an amount which was anticipated to reflect actual invoice prices paid for drugs.[12] *See* 56 Fed. Reg. at 59525. The Secretary's observation that physicians had access to reduced prices and discounts further supports the notion that the Secretary, in adopting EAC, was trying to capture the benefit of such reduced prices. *See* 56 Fed. Reg. at 25800-25801; *id*. at 59524-59525.[13]

Second, the Secretary established an alternate proxy for reasonable charges based on national average wholesale prices. While carriers would, as a practical necessity, refer to Red Book for wholesale pricing data, there is nothing in the regulatory history to suggest that the Secretary intended to be bound by any particular published data. Rather, the published data was a resource to the Secretary in setting the agency's national average wholesale price for payment

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[12] To determine a drug's EAC, the Secretary recommended that carriers survey a sample of physicians to obtain cost information, or alternatively, periodically request that physicians provide cost information with their drug payment claims. 56 Fed. Reg. at 59525.

[13] Moreover, it is telling that in setting the payment limit, the Secretary found support in her "inherent reasonableness" authority, under which she could establish limits on the reasonable charge for an item or service if the charge is determined to be grossly in excess of the *acquisition cost* for the item. 56 Fed. Reg. at 25800.

purposes. This is most plainly illustrated by the Secretary defining the national average wholesale price for multiple-source drugs as the *median* price for all generic sources of the drug. See 42 C.F.R. § 405.517 (1992). By selecting the median, the Secretary clearly treated the published prices simply as a source of data to be used to set the national AWP. Likewise, years later when the Secretary disseminated to Medicare carriers and intermediaries data that had been gathered by DOJ and the National Association of Medicaid Fraud Control Units, the Secretary again regarded the data as an "alternate source of average wholesale price data for certain drugs." Program Memorandum, Intermediaries/Carriers; Transmittal AB-00-86 (Sept. 8, 2000).[14]

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[14] As described by the Secretary:

> They are an *alternate source of average wholesale price data* for certain drugs, which has recently become available to HCFA . . . These data are from wholesalers' catalogs that list the prices at which the wholesaler sells the respective products. The DOJ has indicated that these are more accurate wholesale prices for these drugs. Furthermore, the DOJ has indicated that because purchasers often receive further discounts below the advertised wholesale catalog price, either from a wholesaler or from the drug manufacturer directly, actual acquisition costs may be lower.
> . . .
> Section 1942(o) and 1833(a)(1)(S) of the Social Security Act (the Act) requires the Medicare program to set payment allowances for drugs and biologicals at the lower of the actual amount billed or 95 percent of the average wholesale price. The attached data represent *another source of average wholesale prices* for the products on the attached list. Therefore, use of this new source of average wholesale prices in [the Attachment] is not an inherent reasonableness adjustment under paragraphs (8) and (9) of section 1842(b) of the Act.

Id., available at www.cms.hhs.gov/transmittals/downloads/ab0086.pdf#search=%22Transmittal%20AB-00-86%22>.

Third, the final rule reflected the Secretary's continued belief, as of 1991, that the wholesale price data published in Red Book and other national drug listings generally represented a comprehensive source and indicia of market prices. The Secretary also observed that a significant number of oncologists had submitted comments stating that not all drugs were discounted off the published AWP and that individual physicians could not garner the types of discounts that pharmacies or large practices could. 56 Fed. Reg. at 59524. The Secretary understood that Red Book and the other wholesale price guides updated their information monthly, and thus believed that the published wholesale prices were a source of acquisition costs of *some* physicians and therefore could be used to calculate Part B drug payments.

II. The Words "Average Wholesale Price" As Used In the Balanced Budget Act of 1997 Should Be Interpreted According to Their Plain Meaning

A. Application of the Plain Meaning Rule of Construction Is Appropriate Here

In 1997 Congress enacted the Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, 111 Stat. 462-463 (1997), making a number of significant changes to the Medicare and Medicaid programs. Section 4556 of the BBA amended section 1842 of the Medicare Act, 42, U.S.C. § 1395u, to add the following subsection, effective January 1, 1998:

> (o)(1) If a physician's, supplier's, or any other person's bill or request for payment for service includes a charge for a drug or biological for which payment may be made under [Part B] and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.

There can be little doubt that "average wholesale price" is susceptible to a plain meaning interpretation. "Average" is defined in Webster's Third New International Dictionary of the

English Language (3d ed.1961) (1993 prtg.) as "1: equaling an arithmetic mean; 2: approximating or resembling an arithmetic mean specif. in being about midway between extremes: not out of the ordinary for members of the group under consideration." *Id*. at 150. "Wholesale" is defined as "of, relating to, or engaged in the sale of goods or commodities in quantity for resale." *Id.* at 2611. "Price" is "the amount of money given or set as the amount to be given as a consideration for the sale of a specified thing." *Id*. at 1798. In the context of this case, these definitions are reasonably clear. Whatever ambiguities might be said to attend these words, they are not relevant at this juncture. Here the Plaintiffs allege that the Defendants reported falsely inflated prices that bore no reasonable relation to real prices. No amount of ambiguity in these words can provide legal support for such conduct.

The starting point in statutory construction is the plain meaning. "When a statute speaks with clarity to an issue judicial inquiry into its meaning, in all but the most extraordinary circumstances, is finished." *Estate of Cowart v. Nicklos Drilling Co*., 505 U.S. 469, 475 (1992); *see Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 450 (2002); *General Motors Corp. v. Darling's*, 444 F.3d 98, 108 (1st Cir. 2006); *United States v. Green*, 407 F.3d 434, 442 (1st Cir. 2005). In addition, "[i]n interpreting statutes [the court] must adopt the definition most consistent with the statute's purpose." *United States v. Lachman*, 387 F.3d 42, 51 (1st Cir. 2004); *see also Rolland v. Romney*, 318 F.3d 42, 48 (1st Cir. 2003) ("the plain meaning of the statutory language, as derived from the whole of the statute, including its overall policy and purpose, controls.").

In this case, the plain meaning interpretation of "average wholesale price" comports with the Medicare statute and its general payment objectives. As noted above, a consistent and

overarching objective of the Medicare statute has been to reimburse for drugs and biologicals based upon standards of "reasonable charges" and "reasonable cost." 42 U.S.C. §§ 1395l(a)(1), 1395x(v); *see* S. Rep. No. 404, 89th Cong., 1st Sess. (1965), *reprinted in* 1965 U.S.C.A.A.N. at 1985. As the 105th Congress was no doubt aware, the agency had issued regulations interpreting these statutory standards by tying reimbursement with respect to drugs to estimated acquisition cost and providers' customary charges. 40 Fed. Reg. 32284, 32302 (July 31, 1975) (MAC rules);[15] 56 Fed. Reg. 59502, 59621 (Nov. 25, 1991) (promulgation of "national average wholesale price" standard); *and see* 56 Fed. Reg. at 25800 ("Medicare policy, since the beginning of the Medicare program, has been to base payments for 'incident to' drugs on the estimated acquisition costs."). Interpreting the statute to require reimbursement on the basis of meaningful average wholesale prices furthers the statutory objective of reimbursing "reasonable charges." Interpreting it to provide for reimbursement on the basis of fictitious prices surely does not.[16]

Because the meaning of the statutory language is clear for present purposes, resort to legislative history is unwarranted. *See generally*, *BedRoc Limited, LLC v. United States*, 541

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[15] As noted above, the MAC regulations were eliminated in 1987. *See* 52 Fed. Reg. 28648.

[16] A plain meaning of "average wholesale price" is largely consistent with the definition that the Secretary proposed in 2003. *See* 68 Fed. Reg. 50428, 50433 (Aug. 20, 2003):

> W]e propose to define the AWP of a drug to be the widely available market price. The widely available market price would be the price that a prudent physician or prudent supplier would pay when purchasing the drug from common sources . . . . The widely available market price would not be a list price that is commonly discounted, but would be the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers.

U.S. 176, 186-187 & n.8 (2004); *Arnold v. United Parcel Service, Inc.*, 136 F.3d 854, 858 (1st Cir. 1998). In the event the Court were to consider legislative history, however, the history is not inconsistent with the conclusion that "average wholesale price" should be accorded its plain meaning. The House Budget Committee Report that accompanied the bill that became the BBA of 1997 (H.R. 2015) noted that HHS-OIG reports had shown that the published AWPs had strayed from being a reliable data source for acquisition costs. H. R. Rep. No. 149, 105th Cong., 1st Sess. 1354 (1997). The report then stated:

> The Committee intends that the Secretary, *in determining the average wholesale price*, should take into consideration commercially available information including such information as may be published or reported in various commercial reporting services. The Committee will monitor AWPs to ensure that this provision does not simply result in a 5% increase in AWPs.

Id. (emphasis added). It is apparent that the House Budget Committee understood that the *Secretary*, not manufacturers or publishers, was charged with "determining average wholesale price." While the House recommended that the Secretary "take into consideration" published sources, the BBA did not mandate the adoption of published prices by the Secretary. The Committee viewed the amendment to section 1842 as a cost control measure, as well as a way to align Medicare payments more closely with reasonable charges or market prices.

Aside from establishing a new ceiling to Part B drug payments, nothing on the face of the statute or in the legislative history reflects a congressional intent to depart from the "reasonable charge" regulatory scheme already in place since 1992. Instead, as Judge Stearns of this Court noted:

> [i]t is far more likely that by setting the Medicare reimbursement rate below the AWP, Congress took a tentative step towards using Medicare's purchasing power as a means of driving down the cost

> of prescription drugs to the Medicare program. "Average," after all, means that in a competitive market, some prices will be higher and some lower than the median. Congress might have wished to put Medicare on the lower rung of the equation.

In re: Lupron Marketing and Sales Practices Litigation, 295 F. Supp.2d 148, 163 (D. Mass. 2003).

B. The Defendants' Arguments Are Unpersuasive

The Track 1 Defendants raise a number of arguments why the Court should not adopt the "plain meaning" construction of average wholesale price. None is persuasive.

First, the Track 1 Defendants contend that Congress adopted a "technical term of art" when it incorporated "average wholesale price" into the Medicare Act and, therefore, the Court should construe the term in accordance with the industry understanding. This argument lacks merit. Only in rare circumstances will a court depart from the presumptive plain meaning canon of statutory construction and find that a statutory term is to be construed as a "technical term of art." *See Lachman*, 387 F.3d at 53. Such a departure is warranted only where the technical term has a "well-defined" and "well-accepted" understanding within the relevant industry or trade. *See Corning Glass Works v. Brennan*, 417 U.S. 188, 201-202 (1974) (adopting "well-defined" and "well-accepted" industry understanding of "working conditions" when construing Equal Pay Act); *see also McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 342 (1991) (adopting "seaman" as maritime term of art); *Louisiana Public Service Comm'n v. FCC*, 476 U.S. 355, 371-372 (1986) (holding that "charges," "classifications," and "practices" are "terms often used by accountants, regulators, courts and commentators to denote depreciation treatment"); *Commonwealth of Massachusetts v. Blackstone Valley Electric Co.*, 67 F.3d 981, 986 (1st Cir.

1995) (declining to adopt a "technical term of art" interpretation of "cyanide" given conflicting expert testimony within scientific community).

In this case, the Track 1 Defendants cannot credibly suggest that the "well-defined" or "well-accepted" definition of "average wholesale price" within the pharmaceutical industry was that AWP was whatever was published in the national price listings, without any boundaries whatsoever. Without some uniform industry understanding of the term, the Court should reject the Track 1 Defendants' interpretation of "average wholesale price" as an industry "term of art." *See Blackstone Valley Electric Co.,* 67 F.3d 981 at 986 (declining to adopt a "technical term of art" interpretation of "cyanide" where "scientific community is not a monolithic entity that has spoken here in a single authoritative voice.") (internal quotations omitted).

Nor does this case provide the circumstances at issue in *Corning.* In that case, the Court held that the term "working conditions" should be construed in accordance with the "well-defined and well-accepted principles of job evaluation" in the industry. *Corning*, 417 U.S. at 201. The Court's opinion was informed in no small part by the legislative history of the Equal Pay Act, which reflected Congress's incorporation of specific language proposed by the industry. *Id.* Accordingly, the Court held that using the "term of art" approach was "particularly salutary where . . . the legislative history reveals that Congress incorporated words having a special meaning within the field regulated by the statute so as to overcome objections by industry representatives that statutory definitions were vague and incomplete." *Corning*, 417 U.S. at 201-202.

The circumstances surrounding Congress's adoption of "average wholesale price" are a far cry from those in *Corning*. Nothing in the BBA's legislative history suggests a substantive

dialogue between the pharmaceutical industry and Congress on the meaning of "average wholesale price" or how that term was to be used for setting Part B drug payments. Nor is there any indicia in the legislative history, much less in the final amendment, that Congress intended to supplant the existing "reasonable charge" payment scheme and to allow the publishers of the wholesale price guides (and thereby the drug manufacturers) to define, as a matter of law, the limits of Part B drug payments. The reason for amending the Medicare statute was to achieve payment rates closer to acquisition costs and to lower Part B drug payments in light of government studies indicating that "Medicare ha[d] paid significantly more for drugs and biologicals than physicians and pharmacists pa[id] to acquire such pharmaceuticals." H. R. Rep. No. 149, at 1354.

Finally, the Defendants' "technical term of art" argument must fail because that construction of "average wholesale price" not only contravenes the Medicare Part B payment scheme and its objectives, *see* Part II.A above, it also runs against public policy. The Defendants' interpretation would put into the hands of private entities the unfettered power to set the rates at which government-funded payments are made to those entities' customers. There is no basis to support such an interpretation. In contrast, the position urged by the Secretary here comports with a clear congressional intent to base payments on "reasonable charges" and advances the basic public policy favoring fiscal prudence.

Second, the Track 1 Defendants claim that the plain meaning approach is inconsistent with the Medicare statute insofar as it could result in Medicare reimbursing physicians less than their actual acquisition costs for drugs. This argument is flawed, however, because nothing in the Medicare Act or regulations guarantees that Medicare will reimburse 100 percent of a

provider's costs, no matter how improvidently those costs are incurred. While the Secretary obviously has an interest in ensuring that Part B beneficiaries have access to needed medication, he has an equally compelling interest in protecting the financial integrity of the program and ensuring that Medicare dollars are spent prudently. To that effect, Congress and the Secretary have always set limits to what would be considered "reasonable" for Part B payment purposes. Such limits, while creating incentives for suppliers to act cost-consciously, also necessarily create the possibility that some physicians will charge Medicare more than it is willing to pay. The MAC system provides one example where the Secretary set a payment limitation that could result in a supplier being paid less than his actual acquisition costs. The current ASP system provides another.

Third, the Track 1 Defendants also argue that AWP is a very complicated term and that somehow they were incapable of reporting a price without detailed federal guidance. This is a red herring. The Defendants easily could have, in good faith, reported a price that fell within the rational boundaries of the term "average wholesale price," whether they approached the term mathematically (as a mean or median) or more conceptually (a typical price not "out of the ordinary"). Indeed, as the overview of the Medicare program reflects, it is not uncommon for Congress or the Secretary to employ broad standards to set Medicare payments.[17] That these

[17] The Medicare reimbursement and payment scheme contains many examples where the Secretary relies upon providers, suppliers, and others that deal with the Government, to exercise their rational, good faith judgment in deciding whether and what to bill Medicare. In the Part A context, for example, hospitals are required to exercise their judgment in identifying those reasonable costs that were allocable to the care of Medicare patients. *See* 42 U.S.C. §§ 1395f(a), 1395x(v)(1)(A). Likewise, physicians in the Part B context are required to certify in their requests for Medicare payment that the services rendered "were medically indicated and necessary for the health of the patient" and that any "incident to" services were "of kinds commonly furnished in physician's offices." *See* Form CMS-1500, available at

(continued...)

standards may result in a range of costs or charges, as opposed to a mathematically precise value, neither renders those standards meaningless, nor undercuts Medicare payment goals and objectives. Moreover, by 1991, manufacturers were reporting to the Secretary average manufacturer price data, which reflected a weighted average of prices they charged wholesalers for drugs sold in the retail class of trade. *See* 42 U.S.C. § 1396r-8. For the Defendants to suggest that they were incapable of reporting a price that was reflective of what suppliers were actually and generally paying for their drugs strains credulity.

[17](...continued)
www.cms.hhs.gov/cmsforms/downloads/cms1500.pdf.

CONCLUSION

For the reasons stated above, this Court should construe "average wholesale price" in accordance with its plain meaning, which comports with the Medicare Act and the programmatic objective of paying for Part B drugs based on reasonable charge principles.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "Brief of United States As Amicus Curiae" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

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